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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,860	08/29/2001	Richard E. Rothman	001107.00185	5063

22907 7590 03/19/2007

BANNER & WITCOFF, LTD.
1100 13th STREET, N.W.
SUITE 1200
WASHINGTON, DC 20005-4051

EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/940,860	ROTHMAN ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,4-23,33 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23 and 34* is/are allowed.

6)☒ Claim(s) *2,4-22 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 August 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's response to the office action filed on, 2007 is considered and acknowledged.

Status

2. Claims 2, 4-23, 33-34 are pending and are considered for examination in this office action. This action is made Final. All arguments have been thoroughly reviewed and deemed unpersuasive for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objections to the Drawings

3. The Drawings are objected because of the following informalities:

(i) This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply the requirements of 37 CFR 1.821 through 1.825.

The instant application recites sequences that are not identified by SEQ ID No. (see at least Figure 1A and 1B) recite a nucleic acid sequence / amino acid sequence with more than 10 nucleotides or 4 amino acids, which is not identified by SEQ ID NO.). Applicant is required to represent each sequence by a SEQ ID No.

The drawings are objected to because the sequence in Fig. 1A and Fig. 1B are not identified by SEQ ID No. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the

appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Appropriate correction is required.

Response to arguments:

4. With regard to the rejection of claims 2, 4, 8, 20-22, 33 under 35 USC 103(a) as being obvious over Steinman in view of Stratagene Catalog, Applicants' arguments are fully considered and found unpersuasive. Applicants' arguments are based on previous prior art (DeFelippes et al.) and argue that DeFilippes et al. disclose that the digestion of PCR reaction mixture was not routinely successful and it did not always completely inactivate the template and thus Alu I does not effectively eliminate contaminating DNA and DeFelippes teaches away from the instant invention. Applicants also argue that the rejection over Steinman in view of Stratagene should be withdrawn because the teachings of DeFelippes remain relevant to the assessment of non-obviousness. Applicants' arguments are fully considered and found unpersuasive because the situation in the instant rejection is not the same as in DeFelippes, First, the obviousness was made based on the ability of the type II restriction endonucleases to eliminate DNA contamination as shown by Steinman et al. and the Stratagene Catalog was used to show that the

AluI is an equivalent enzyme to said type II restriction endonucleases and it is obvious to one skilled in the art would have used such equivalent enzymes to eliminate DNA contamination in PCR reagents.

Second, the instant claims require AluI and the arguments are based on disadvantages of using said enzyme. As noted in MPEP 2112 "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In In re Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004). In the instant case, the unappreciated property of use of Alu I and the claiming the new use of the composition is inherent and does not render the claims patentable. Thus the use of type II restriction endonucleases for complete elimination of DNA contamination in PCR reaction mixture is an inherent property of type II restriction endonucleases and use of such equivalent enzymes is considered obvious over the prior art. Further if the use of AluI is other than a routine experimentation, as noted in *In re Aller*, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the use of an equivalent type II endonuclease as AluI digestion performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected

in any way as compared to the closest prior art. As stated in MPEP 716.02 (d) "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens , 622 F.2d 1029, 206 USPQ 289, 296 (CCPA 1980)". Here, Steinman expressly teach use of type II restriction endonucleases to decontaminate PCR reaction mixture and Stratagene Catalog provides several equivalent type II restriction endonucleases that are within the scope of the instant claims and there is no evidence or showing that the use of AluI is other than a routine optimization. Therefore for the reasons above, the rejection is maintained.

5. With regard to the rejection of claims 5-7 and 9-19 under 35 USC 103(a) as being obvious over Steinman in view of Stratagene, further in view of Hoshima, Applicants' arguments are found unpersuasive. As discussed above the combination of Steinman in view of Stratagene does make the instant claims obvious and the modification of the method further in view of Hoshima renders the claims obvious. With regard to the arguments base don teaching away, Examiner notes that MPEP 2145, "A prior art reference that "teaches away" from the claimed invention is a significant factor to be considered in determining obviousness; however, "the nature of the teaching is highly relevant and must be weighed in substance. A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994), a teaching away, is a significant factor to be considered as "teaching in". In the instant context, the use of Alu I is a significant factor considered as to teaching in. Thus

Hoshima does make the instant claims obvious as dicussed in the rejection. The rejection is maintained herein.

Conclusion

Claims 23, and 34 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru
Primary Examiner
Art Unit 1637

Prabha Chunduru
SURYAPRABHA CHUNDURU 3/15/07
PRIMARY EXAMINER